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09/750,424	12/28/2000	Adrian Auf Der Maur	27656/37021	7858

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EXAMINER
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WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 11/21/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application N .

09/750,424

Applicant(s)

DER MAUR ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-30 and 39-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

***Election/Restrictions***

Applicant's election of Group VIII (claims 31-38) in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-30 and 39-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

***Status of Claims***

Claims 1-41 are pending.

Claims 1-30 and 39-41 are withdrawn consideration, as stated above.

Claims 31-38 are under examination.

***Specification***

The disclosure is objected to because of the following informalities: Incomplete sentence at page 1, last paragraph.

Appropriate correction is required.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors

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(typographical, grammatical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 31 is unclear as to how a fusion **protein** encodes an **intrabody** framework. (A protein does not encode another protein.) Furthermore, "wherein" is not a positive, manipulative process step. It is not clear as to the step defined by the "wherein" clause.

B. Claim 33 is indefinite as to the "selectable" activity of the marker protein i.e., the basis or standard by which said marker is considered to be of selectable activity. [Claim 34 appears better].

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C. Claims 32 and 33 are unclear as to whether "marker protein" is the same or different from the base claims "marker system".

D. Claims 35-38 recitation of a "DNA binding protein" is unclear if this refers to the marker system e.g., claim 35. The use of inconsistent terminologies such as "marker system", "transactivation system", and "survival allowing marker" provides for confusion as to whether the same thing is being claimed.

E. Claim 36 broadens the base claim with the recitation of cells expressing different marker. [Note the specification refers to this claim as a different embodiment from claim 31].

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 31-38 are rejected under 35 U.S.C. 102(a) as being anticipated by Worn et al (Jrnl. of Biological Chemistry) or Taliana et al (Jrnl. of Immunological Methods).

Worn at page 2795 up to page 2796, Experimental Procedures, discloses a method of cellular assay system for measuring the activity of cytoplasmically expressed anti-GCN4scFV intrabodies, comprising transforming yeast, *S. cerevisiae* (suitable host cells as claimed) with a library of anti-GCN4 scFv and beta-gal (marker system as claimed). See specifically the Experimental Procedures at page 2796. Accordingly, the specific method steps of Worn employing specific components fully meet the broad claimed process steps using broad components therein.

For the rejection under Taliana, see the rejection under Hoffler, *infra*.

***Priority***

Applicants cannot rely upon the foreign priority papers to overcome this rejection because a copy of said priority papers has not been made of record.

Claims 31-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Hoffler et al (US 20030017149).

Hoffler et al discloses at paragraph [0001] a method for screening DNA construct libraries for those which encode single-chain fragments of immunoglobulin variable domains (sFvs) (intrabodies, as claimed) having specificity for desired antigens in vivo using the activity of a transcriptional activator. At paragraph [0101], Hoffler discloses the fusion protein comprising at least one nuclear localization sequence (NLS). Hoffler at paragraph beginning at 0183] provides a detailed description of the method i.e., an example method for isolating single chain monoclonal antibody fusion reagents that target constitutive transcriptional activation peptide domains to endogenous signal-responsive transcriptional regulatory proteins wherein the CREB phosphorylation BOX peptide domain (CREB/P-BOX) is fused to the LexA DBD and acts as the LexA DBD/protein antigen X fusion of interest (the "bait") for

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screening immunoglobulin variable regions in this system. See FIG. 1. At paragraph [0184] Hoeffler discloses, a single chain antibody fusion reagent molecule targets the CREB sequence in the antigen fusion, transcription factor function is reconstituted and the reporter genes (marker system, as claimed) are activated allowing growth on selective media lacking histidine, as well as demonstrating beta-galactosidase activity. Positive interactions can be detected in this particular embodiment by selecting on plates lacking histidine, followed by a second screen for beta-galactosidase expression. Identification of the immunoglobulin fusion reagent (antibody/VP16 fusion, for example) which binds the LexA DBD/CREB/P-BOX antigen fusion is the ultimate goal of the screening protocol. Moreover, once isolated, the nucleic acid sequences which encode the immunoglobulin fusion reagent can be cloned into a mammalian expression vector and the targeting of CREB in the nucleus may be ascertained using reporter genes and endogenous genes that are known to harbor consensus camp responsive element (CRE) motifs. Accordingly, the specific process steps of Hoeffler fully meet the broad claimed invention.



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Claims 31-38 are rejected under 35 U.S.C. 102(b) as being anticipated by either Visintin et al (PNAS) or Cattaneo et al (Tibtech).

Each of these references basically discloses the same method as Worn above and as the instant claims. See Cattaneo et al, the entire document, specifically, page 119, col. 1 up to col. 2.

See Visintin et al specifically The Materials and Methods section at page 11723. Accordingly, each of these references which recite specific steps and components therein fully meet the broad claimed invention.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-7924.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw

November 17, 2003